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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,801	01/17/2006	Jean-Francois Garbe	3338.68US01	4287
24113	7590	07/18/2006	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.			ADAMS, AMANDA S	
4800 IDS CENTER			ART UNIT	
80 SOUTH 8TH STREET			PAPER NUMBER	
MINNEAPOLIS, MN 55402-2100			3731	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/530,801	Applicant(s) GARBE, JEAN-FRANCOIS	
	Examiner Amanda Adams	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) ¹⁰⁻²¹~~1-21~~ is/are pending in the application.
- 4a) Of the above claim(s) ~~1-9~~ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10-21 is/are rejected.
- 7) ☒ Claim(s) 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19 and 20 each recite the limitation "claim 2" in line 1. There is insufficient antecedent basis for this limitation in the claim, as the original claim 2 has

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been cancelled. It has been assumed that the applicant meant "claim 11." Appropriate correction is required.

3. Claim 21 recites the limitation "claim 6" in line 1. There is insufficient antecedent basis for this limitation in the claim, as the original claim 2 has been cancelled. It has been assumed that the applicant meant "claim 15." Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10-12, 13, and 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496) and further in view of Sancoff et al (US 6,682,540).
3. Regarding claims 10 and 12, Jacobs et al discloses the invention substantially as claimed including a sleeve capable of expansion between a minimal-diameter configuration and a stable expanded configuration with a series of fixation barbs arranged in a radial configuration about the proximal and distal ends and intermediate portions of the sleeve (figure 10B), wherein the sleeve is meant to be used at either end of a graft or prosthesis to connect it to a duct or vessel within the body.
4. Jacobs et al fails to disclose the sleeve being comprised of mesh, and curved barbs. However, Suyker et al teaches a mesh sleeve with diamond-shaped cutouts with

a plurality of barbs located at the intersections of the diamond mesh structure, and barbs of a curved configuration (column 3, lines 49-56). A mesh sleeve will improve the expansion capabilities of the sleeve, therefore it would have been obvious to have a mesh sleeve on the vascular device of Jacobs et al. Having curved barbs on the intermediate portion of the sleeve combined with straight barbs on the ends of the sleeve improves the sleeve's ability to engage the vessel and graft, without becoming entangled with itself upon expansion. Therefore it would have been obvious to configure the barbs in such a way wherein the intermediate barbs are curved while the other barbs are straight.

Regarding claims 10, 15, 17, and 21, Jacobs et al in view of Suyker et al teach the invention substantially as claimed except for failing to teach the particular shape of the barb. However, Sancoff et al teaches that a barb can be shaped with a circular base section and a conical tip (column 5, lines 5-10). Due to lack of criticality in the specification, the trihedral-shaped tip on each barb was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb tri-hedral because it is capable of working equally as well as a conical shaped barb tip. Also due to lack of criticality in the specification, the angle of the tip on each barb between 0 and 10 degrees, or 5 degrees to be more specific, and was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb at an angle between 0-10 degrees because it is capable of working

equally as well as any other well-known barb angle.

5. Regarding claim 13, due to lack of criticality in the specification, expanding the sleeve to a final diameter which is greater than twice its initial diameter was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to expanding the sleeve to twice the diameter or just under twice the diameter. Therefore, it would have been obvious to state that the sleeve must expand to at least twice the diameter of its initial unexpanded diameter.

6. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496), further in view of Sancoff et al (US 6,682,540) and further in view of Chobotov et al (2003/0120338).

7. Regarding claim 11, Jacobs et al in view of Suyker et al disclose the invention substantially as claimed above except for failing to disclose the device being made of steel. However, Chobotov et al teaches a similar device wherein the material used to make it can be steel (page 5, paragraph 65). Many stents are made of stainless steel as it will not corrode in the body. Therefore it would have been obvious to have a connecting device comprised of steel.

8. Regarding claim 16, Chobotov et al teaches that the length of each barb can vary within a single device (page 6, paragraph 80). This is so that the barb lengths can be of the appropriate length for the thickness of the multiple or single layers that it has to pierce through. Therefore it would have been obvious to have barbs of a shorter length at the ends than in the intermediate portion of the device, in order to prevent damage to

surrounding tissues.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al (US 5,941,908) in view of Jacobs et al (US 2001/0044637), further in view of Sancoff et al (US 6,682,540).

10. Goldsteen et al disclose the method substantially as claimed including the steps of intubing a first end of a prosthesis in the extremity of a body duct, setting a connecting device in place by inflating a balloon catheter, intubing a second end of the prosthesis in a body duct and setting in place a second connecting duct (col 2, lines 56-58; column 4, lines 27-47). Goldsteen et al also disclose a connecting device being a mesh sleeve that is capable of radial expansion between a minimal-diameter configuration and a stable expanded configuration (col. 2, lines 25-27). Goldsteen et al do not disclose barbs on the sleeve. However, Jacobs et al teach a sleeve capable of expansion between a minimal-diameter configuration and a stable expanded configuration with a series of fixation barbs arranged in a radial configuration about the proximal and distal ends and intermediate portions of the sleeve (figure 10B), wherein the sleeve is meant to be used at either end of a graft or prosthesis to connect it to a duct or vessel within the body. Barbs on the sleeve provide a more stable connection between the device and the graft or vessel. Therefore it would have been obvious to use the sleeve of Jacobs et al with the method disclosed by Goldsteen et al.

Regarding the shape of the barbs, Goldsteen et al in view of Jacobs et al teach the invention substantially as claimed except for failing to teach the particular shape of

the barb. However, Sancoff et al teaches that a barb can be shaped with a circular base section and a conical tip (col. 5, lines 5-10). Due to lack of criticality in the specification, the trihedral-shaped tip on each barb was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb tri-hedral because it is capable of working equally as well as a conical shaped barb tip.

11. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496), further in view of Sancoff et al (US 6,682,540) , further in view of Chobotov et al (2003/0120338) and further in view of Berg et al (US 6,451,048).

12. Jacobs et al in view of Suyker et al teach the invention substantially as claimed except for failing to teach a method of attaching the barbs to the device. However, Berg et al teach attachment of the barbs to the device by either soldering or gluing (figures 4a and 4b, respectively). These are both well-known methods of attaching components to make a medical device. Therefore it would have been obvious to attach the barbs to the device in this manner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ASA 6/30/06


ANH Tuan T. NGUYEN
SUPERVISORY PATENT EXAMINER

7/10/06